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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

KFX MEDICAL CORPORATION, a)	Case no. 11cv1698 DMS (BLM)
Delaware corporation,)	
Plaintiff and Counterdefendant,)	MEMORANDUM OF POINTS AND
v.)	AUTHORITIES IN SUPPORT OF
ARTHREX, INCORPORATED., a Delaware)	PLAINTIFF'S MOTION TO (A)
corporation,)	DISMISS DEFENDANT'S
Defendant and Counterclaimant.)	COUNTERCLAIM FOR
)	INEQUITABLE CONDUCT IN
)	CONNECTION WITH U.S. PATENTS
)	8,100,942 AND 8,109,969; (B) STRIKE
)	THE CORRESPONDING
)	AFFIRMATIVE DEFENSE; AND (C)
)	EXTEND TIME TO ANSWER
)	REMAINING COUNTERCLAIM
)	ALLEGATIONS
)	
)	
)	Date: July 13, 2012
)	Time: 1:30 p.m.
)	Courtroom 10, 2 nd Floor
)	Honorable Dana M. Sabraw

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I. INTRODUCTION

Plaintiff KFx invented new bone anchors and methods that enable tissue fixation with a minimum of suturing and manipulation. KFx brought this lawsuit against Defendant Arthrex for infringement of U.S. Patent No. 7,585,311 (“the ‘311 patent”) entitled, “System and Method for Attaching Soft Tissue to Bone.” After the filing of the lawsuit, KFx was awarded two additional patents on its novel surgical methods, U.S. Pat. Nos. 8,100,942 (“the ‘942 patent”) and 8,109,969 (“the ‘969 patent”). These patents were recently added to the lawsuit.

The KFx patents generally relate to improved surgical methods of attaching soft tissue to bone, e.g., as in a torn rotator cuff, using knotless suture capturing anchors. The methods include passing a length of suture from a first anchor over the soft tissue to a second anchor inserted beyond the edge of the soft tissue, tensioning the suture and securing it to the second anchor without tying knots.

This motion is directed to Arthrex’s counterclaim and affirmative defense charging KFx and its patent counsel with inequitable conduct in obtaining these two additional patents.¹ Inequitable conduct is an extremely serious charge that includes elements of deceit and material misrepresentation or omission. Because inequitable conduct is akin to fraud, a party must plead inequitable conduct with particularity and satisfy Rule 9(b) of the Federal Rules of Civil Procedure. The Federal Circuit recently explained that “the habit of charging inequitable conduct in almost every major patent case has become an absolute plague” and it is “a doctrine that has been overused to the detriment of the public.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289-90 (Fed. Cir. 2011) (*en banc*) (internal quotations omitted). The Federal Circuit noted how it “increas[es] the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost.” *Id.* at 1288. In light of these “far reaching consequences”, the Federal Circuit in

¹ Arthrex also alleges KFx’s ‘311 patent is unenforceable for inequitable conduct. That defense is more appropriately resolved by considering evidence outside the pleadings and will therefore be the subject of a summary judgment motion.

1 *Therasense* imposed a higher legal standard for both elements of inequitable conduct,
2 materiality and intent. *Id.* at 1290.

3 Arthrex's allegations raise three theories of alleged inequitable conduct based on: (1)
4 failure to draw the Examiner's attention to certain information that was properly disclosed in
5 an Information Disclosure Statement ("IDS") and considered by the Examiner during
6 examination; and (2) "failure to disclose the actual priority date" for the claims of one of the
7 KFx continuation applications; and (3) failure to withdraw a patent application from issue so
8 that Arthrex's Invalidity Contentions in this lawsuit would be considered by the PTO and not
9 merely placed in the application file.

10 Arthrex's theories of inequitable conduct find no support in the case law and fall far
11 short of the strict requirements of *Therasense*. Because Arthrex's pleading fails to state a
12 viable claim of inequitable conduct as to the '942 and '969 patents, its inequitable conduct
13 counterclaim as to these patents should be dismissed and the corresponding affirmative
14 defense stricken.

15 **II. LEGAL STANDARD**

16 **A. Motions to Dismiss and Strike under Rules 12(b)(6) and Rule 12(f) of Federal** 17 **Rules of Civil Procedure**

18 "To survive a motion to dismiss, a [pleading] must contain sufficient factual matter,
19 accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 566
20 U.S. 662, 129 S. Ct. 1937, 1949 (2009) (internal quotations omitted). The Supreme Court has
21 suggested a two-step approach to a motion to dismiss: A court first distinguishes between the
22 well-pleaded factual allegations and those allegations "that, because they are no more than
23 conclusions, are not entitled to the assumption of truth." *Id.* at 1950. Then, assuming the
24 veracity of only the well-pleaded factual allegations, the court must "determine whether they
25 plausibly give rise to an entitlement to relief." *Id.* "Threadbare recitals of the elements of a
26 cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949.

27 Rule 12(b)(6) refers to the dismissal of "claim[s]." Fed. R. Civ. P. 12(b)(6). Arthrex
28 alleges inequitable conduct both as a claim for relief, e.g. counterclaim, and as an affirmative

1 defense. Pursuant to Rule 12(f) this Court “may strike from a pleading any insufficient
 2 defense.” Fed. R. Civ. P. 12(f). It is proper to strike an affirmative defense where the
 3 defense is insufficient as a matter of law. *See, e.g., Multimedia Patent Trust v. Microsoft*
 4 *Corp.*, 525 F.Supp.2d 1200 (S.D. Cal. 2007).

5 **B. Inequitable Conduct Requires Materiality and Intent**

6 “Inequitable conduct is an equitable defense to patent infringement that, if proved,
 7 bars enforcement of a patent.” *Therasense*, 649 F.3d at 1285. “The substantive elements of
 8 inequitable conduct are: (1) an individual associated with the filing and prosecution of a
 9 patent application made an affirmative misrepresentation of a material fact, failed to disclose
 10 material information, or submitted false material information; and (2) the individual did so
 11 with a specific intent to deceive the PTO [Patent and Trademark Office].” *Exergen Corp. v.*
 12 *Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009).

13 As mentioned above, the Federal Circuit recently heightened the materiality
 14 requirement and tightened the standard for determining intent to deceive. *See Therasense*,
 15 649 F.3d at 1290-96. The requisite materiality to establish inequitable conduct is now “but-
 16 for materiality.” *Id.* at 1291. In other words, the information must be so material that “but
 17 for” the information being withheld from the PTO, the patent would not have been granted.
 18 As for intent, the Federal Circuit held that the party charging inequitable conduct must prove
 19 that the patentee acted with the specific intent to deceive the PTO, and that such specific
 20 intent to deceive must be “the single most reasonable inference able to be drawn from the
 21 evidence.” *Id.* at 1290-1291. The court also made clear that “intent” and “materiality” were
 22 separate requirements, and that a strong showing of materiality cannot buttress a weak
 23 showing of intent, and vice versa. *Id.* at 1290.

24 **C. Pleadings of Inequitable Conduct are Held to a High Standard**

25 Allegations of inequitable conduct must be pleaded with the specificity required by
 26 Rule 9(b) of the Federal Rules of Civil Procedure. *Exergen*, 575 F.3d at 1326–28. To satisfy
 27 the heightened pleading requirements of Rule 9(b), a pleading “must identify the specific
 28 who, what, when, where, and *how* of the material misrepresentation or omission committed

1 before the PTO.” *Id.* at 1328 (emphasis added). “A charge of inequitable conduct based on a
 2 failure to disclose will survive a motion to dismiss **only if** the plaintiff’s complaint recites
 3 facts from which the court may reasonably infer that a specific individual both knew of
 4 **invalidating information** that was withheld from the PTO and withheld that information with
 5 a specific intent to deceive the PTO.” *Delano Farms Co. v. Cal. Table Grape Comm’n*, 655
 6 F.3d 1337, 1350 (Fed. Cir. 2011) (emphases added).

7 **III. ARTHREX’S INEQUITABLE CONDUCT ALLEGATIONS**

8 Arthrex asserts three theories of inequitable conduct with respect to the ‘942 and ‘969
 9 patents that KFx recently added to this case.² First, Arthrex alleges that KFx’s patent
 10 attorney Ryan Melnick committed inequitable conduct by not affirmatively raising certain
 11 information to the specific attention of the Examiner during an interview with the Examiner
 12 or in comments submitted in response to the Examiner’s reasons for allowance. The
 13 information in question, however, was submitted in an Information Disclosure Statement
 14 (“IDS”) and considered by the Examiner during examination.

15 Arthrex’s second theory of inequitable conduct relates to KFx’s claim of priority
 16 included in KFx’s ‘622 continuation application. The ‘622 application referenced a series of
 17 earlier applications, including three provisional applications. The provisional applications do
 18 not disclose all features recited in the ‘622 application claims. Arthrex alleges Melnick
 19 committed inequitable conduct because he “fail[ed] to disclose the actual priority date” for
 20 the ‘622 application.

21 And finally, Arthrex alleges Melnick committed inequitable conduct by not
 22 withdrawing the ‘622 patent application from issuance after Arthrex served its Invalidity
 23 Contentions for the ‘311 patent initially asserted in this case. Arthrex served the Invalidity
 24

25 ² Arthrex’s Third Affirmative Defense alleges inequitable conduct. *See* Arthrex’s
 26 Answer to KFx’s First Amended Complaint and Counterclaims (“Answer”) at ¶¶ 78-168. *See*
 27 Docket Entry 28. The same allegations are repeated in Arthrex’s Third Counterclaim for
 28 Declaratory Judgment of Unenforceability. *See* Answer ¶¶ 23-114. In this Memorandum
 KFx cites to Arthrex’s allegations in the Third Affirmative Defense, namely paragraphs 78–
 168 at pages 6-15 of the Answer.

Contentions for KFx's '311 patent after the examination of the '622 application was closed, namely after the Examiner had allowed the application and after KFx had paid the required patent issue fee. KFx promptly submitted those Invalidity Contentions to the PTO to be placed in the PTO file as provided by Patent Office Rules of Practice (37 C.F.R. §1.97(i)). Arthrex alleges that KFx committed inequitable conduct by submitting the Invalidity Contentions without also affirmatively withdrawing the '622 patent application from issuance so that the Invalidity Contentions could be considered by the Examiner.

The specific allegations relating to these theories of inequitable conduct are discussed in more detail below. For ease of reference, a chronology of the various patent applications and events leading to the '311 patent are included in Appendix A hereto. A chronology of the applications and prosecution events for the '969 and '942 continuation patents are included in Appendix B hereto.

A. The Interview and Information Related to the Millett Article

The first theory of inequitable conduct centers around a publication, which the Answer refers to as the "Millett Article." Answer at ¶ 85. The Millett Article was submitted to the PTO both in connection with the original '311 patent and during examination of the applications leading to the '942 and '969 continuation patents. *Id* at ¶¶ 85, 86; *see also* Bennett Decl. Ex. 1 at 3, Ex. 2 at 39, and Ex. 3 at 74 (listing Millett Article among the References Cited for each of three patents in suit).³ In connection with the continuation applications, KFx also submitted a statement from its CEO, Tate Scott, regarding a conversation Scott had with Dr. Millett, one of the authors of the Millett Article. In the statement, Scott explained that Millett informed him that the "procedures referenced in the 2004 article had been performed in the two years preceding publication for the article" and that "all of the procedures were performed by tying knots as described in the 2004 article." Answer. at ¶¶ 100-101.

³ Although not physically attached to Arthrex's pleading, documents referenced therein may be considered in ruling on a Rule 12 (b)(6) motion to dismiss. *See Branch v. Tunnell*, 14 F.3d 449 (9th Cir. 1994); *Knivel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005).

1 The Millett Article and Scott Statement were both submitted to the Examiner in a
2 December 1, 2011 IDS for each of the ‘620 and ‘622 applications. *See* Bennett Decl. Ex. 4
3 at 115, Ex. 5 at 125. Melnick also conducted an interview with the Examiner on December 1,
4 2011. Answer at ¶ 132. During the interview, the Examiner discussed two prior art
5 references with Melnick, the Thal and Jobe references. *Id.* at ¶ 133. The Thal and Jobe
6 references previously had been applied by the Examiner in the parent ‘007 application. *Id.* at
7 ¶ 134. Arthrex alleges Melnick “diverted the Examiner’s attention from the Scott Statement
8 since the Examiner was led to believe that Thal and Jobe were the most material references
9 disclosed in the December 1, 2011 IDS.” Answer at ¶ 137. According to Arthrex, without
10 having the Scott Statement or the work performed for the Millett Article specifically brought
11 to his attention in the ‘620 and ‘622 applications, the Examiner did not specifically apply the
12 work performed for the Millett Article in rejecting the pending claims. Answer at ¶ 140.

13 The Examiner, however, noted that he did consider the Millett Article and Scott
14 Statement before allowing the ‘620 and ‘622 applications. Bennett Decl. Ex. 8 at 141, 142,
15 (indicating that all references listed in the IDS for the ‘620 application had been considered
16 unless specifically lined through); Ex. 9 at 148, 149 (same for ‘622 application). Shortly after
17 signing off on the IDSs, the Examiner issued notices of allowance in both the ‘620 and ‘622
18 applications. Answer at ¶¶ 144-145.

19 The Examiner cited the following reasons for allowing the claims: “neither Thal nor
20 Jobe disclose after inserting the second anchor, tensioning the first length of suture to
21 compress an area of tissue to bone between the edge of the soft tissue and the first anchor,”
22 and that “[t]he prior art of record nor the prior art at large, alone or in combination, cannot
23 remedy the deficiencies of the Thal and Jobe references and thus the claims are allowed.”
24 Answer at ¶ 146. The Examiner’s reasons for allowing the claims were the same as the stated
25 reasons for allowing the claims of the ‘311 patent. Answer at ¶ 147.

26 According to Arthrex’s allegations, the Millett Article, as well as the work performed
27 for the Millett Article, discloses the subject matter that the Examiner stated was missing from
28 Thal and Jobe. *Id.* at ¶ 148. The Scott Statement, the Millett Article, and the work performed

for the Millett Article therefore were “material to the patentability of the claims of the ‘620 and ‘622 Applications.” Answer at ¶ 149.

After allowance, Melnick filed comments on the Examiner’s statement of reasons for allowance in the ‘620 and ‘622 applications. *Id.* at ¶¶ 151-152. The comments did not refer to the Millett Article, the work performed for the Millett Article or the Scott Statement, *id.* at ¶ 152, which by then had already been considered by the Examiner.

From these allegations, Arthrex contends that KFx committed inequitable conduct as follows:

Mr. Melnick’s failure to bring the Millett Article, the work performed for the Millett Article and the Scott Statement to the attention of the Examiner during the Interview and in the ‘620 Comments or the ‘622 Comments along with Mr. Melnick’s failure to disclose the actual priority date for the ‘622 Application while at the same time diverting the Examiner’s attention to two other references (Thal and Jobe) previously overcome in the ‘077 Application with claim limitations similar to those in the ‘620 and ‘622 Applications was done knowing, deliberately and with the specific intent to deceive the PTO as to which references were the most material.

Answer at ¶ 153.

B. The Priority Date for the ‘622 Application

The specification of the ‘622 application begins with a section titled “Related Applications”, which refers to each of KFx’s prior applications as follows:

This application is a continuation of U.S. application Ser. No. 12/549,105, filed Aug. 27, 2009, which is a divisional of U.S. application Ser. No. 11/143,007, now U.S. Patent No. 7,585,311, filed June 1, 2005, which claims priority to U.S. Provisional Application Nos. 60/576,477 filed on June 2, 2004; 60/610,924, filed on Sep. 17, 2004, and 60/634,174, filed on Dec. 7, 2004; all of which are incorporated herein by reference in their entirety.

See Answer at ¶ 66; *see also* Bennett Decl. Ex. 3 at 99 col. 1, lines 6-13.

Arthrex alleges the ‘622 application claimed priority to one of the three provisional applications KFx filed, namely the second provisional application that was filed September 17, 2004. Answer at ¶¶ 120 and 121; *see also id.* at ¶ 82 (defining “Provisional Application” as the provisional application filed on September 17, 2004). The September 17, 2004 provisional application is the application that preceded the publication of the Millett Article. Answer at ¶ 87; *see also* chronology in Appendix A hereto.

1 Arthrex alleges inequitable conduct because Melnick did not affirmatively inform the
2 Examiner that the claims of the '622 application were entitled to a priority date of September
3 1, 2005, which is the filing date of KFx's regular application filed after the three provisional
4 applications. Answer at ¶ 141. According to Arthrex, had the Examiner known that the '622
5 application was entitled only to a priority date of June 1, 2005, he would have applied the
6 Millett Article to reject the pending claims and would not have allowed the application.
7 Answer at ¶ 143.

8 **C. The '311 Patent Invalidity Contentions**

9 Arthrex alleges that KFx also committed inequitable conduct with respect to the '622
10 application in submitting the Arthrex Invalidity Contentions served in this case for the '311
11 patent. The '622 application had been examined and allowed when Arthrex served its
12 Invalidity Contentions for the '311 patent. See Answer at ¶ 155. The Invalidity Contentions
13 alleged that the claims of the '311 patent were anticipated by information and documents not
14 previously considered by the PTO. *Id.* ¶ 156. Arthrex now alleges in a conclusory fashion
15 that these Invalidity Contentions are material to the '622 application. Answer at ¶ 157.

16 On February 6, 2012, Melnick filed an IDS disclosing the Invalidity Contentions to
17 the PTO, stating "[s]ubmitted herewith in the above-identified application, is an Information
18 Disclosure Statement listing references for consideration" and further requesting that the PTO
19 "[p]lease place these references in the file in accordance with 37 C.F.R. § 1.97(i)" ("Rule
20 97(i)"). Answer at ¶¶ 158-160.

21 Arthrex alleges that Rule 97(i) indicates that the references would not be considered
22 and that Mr. Melnick knew that references would not be considered by the PTO when he
23 stated that the references were being submitted "for consideration." Answer at
24 ¶¶ 161-162. Because examination of the '622 application was closed when Arthrex served
25 the '311 patent Invalidity Contentions, KFx would have needed to file a petition to withdraw
26 the '622 application from issue along with a Request for Continued Examination or a
27 Continuation Application in order to have the Invalidity Contentions considered by the PTO.
28 Answer at ¶¶ 163-167.

In light of these allegations, Arthrex contends that “Mr. Melnick’s knowingly false statement that the Invalidity Contentions were being submitted ‘for consideration’ and his failure to take any of the required actions in order to actually have the Invalidity Contentions considered by the PTO, were done knowingly, deliberately and with the specific intent to deceive the PTO.” Answer at ¶ 168.

IV. ARTHREX’S INEQUITABLE CONDUCT CLAIMS
FOR THE ‘942 AND ‘969 PATENTS SHOULD BE DISMISSED

A. Arthrex Fails to State a Claim Based on a Failure to Bring the Millett Article and Scott Statement to the Specific Attention of the Examiner

1. Arthrex’s Theory Fails as a Legal Matter

In its first theory, Arthrex does not allege that KFx failed to disclose any prior art reference or information to the PTO. Arthrex acknowledges that the Millett Article and the Scott Statement were disclosed in an IDS. Answer at ¶ 85-86 (“The Millett Article is listed as item #147 in the January 2007 IDS.”)⁴ and at ¶ 127 (“The Scott Statement is listed as item #197 in the December 2011 IDS.”). Arthrex instead alleges that KFx committed inequitable conduct because it failed to bring this information to the *specific attention* of the Examiner. This does not state a claim for inequitable conduct as a matter of law.

A party that properly submits a prior art reference or information in an IDS cannot be deemed guilty of withholding material information from the Examiner by not drawing the Examiner’s specific attention to the submitted information. *See Scripps Clinic & Research Found. v. Genentech, Inc.* 927 F.2d 1565, 1582 (Fed. Cir. 1991) (“[w]hen a reference was
 ///

⁴ This paragraph of the Answer states that the Millett Article was submitted in the parent ‘007 application. It was also submitted in the December 1, 2011 IDS in the ‘620 and ‘622 applications. Bennett Decl. Ex. 4 at 115, Ex. 5 at 125. Further, the PTO rules provide that any reference submitted in a parent application is considered to have been submitted in any continuing application claiming priority to the parent application, which is the case here. MPEP § 609.02 (“[t]he examiner will consider information which has been considered by the Office in a parent application when examining: (A) a continuation application filed under 37 CFR 1.53(b), (B) a divisional application filed under 37 CFR 1.53(b), or (C) a continuation-in-part application filed under 37 CFR 1.53(b)”).

1 before the examiner, whether through the examiner's search or the applicant's disclosure, it
2 can not be deemed to have been withheld from the examiner").

3 On circumstances similar, but even less favorable to the patentee than present here,
4 the Federal Circuit has explicitly rejected the theory asserted by Arthrex. In *Fiskars, Inc. v.*
5 *Hunt Mfg. Co.*, 221 F.3d 1318 (Fed. Cir. 2000), the Federal Circuit considered a case where
6 the defendant alleged inequitable conduct based on the patentee's "obligation to stress to the
7 examiner the relevance of [certain prior art disclosed to the Examiner]." *Id.* at 1327. The
8 Federal Circuit rejected this argument, holding that "[a]n applicant can not be guilty of
9 inequitable conduct if the reference was cited to the examiner, whether or not it was a ground
10 of rejection by the examiner." *Id.*

11 In *Fiskars*, the Examiner actually did not consider the allegedly material references
12 submitted by the applicant, and instead drew a line through the references on the listing form
13 indicating that they were not considered. *Id.* at 1327 ("Hunt argues that the examiner did not
14 consider [the reference], pointing to the line drawn through this listing on Form 1449."). The
15 *Fiskars* defendant argued that the Examiner's failure to consider the references "placed on
16 [the patentee] the obligation to stress to the [E]xaminer the relevance of [the reference]." *Id.*
17 The court rejected the argument. Thus, even where the Examiner *did not consider* the
18 allegedly material reference, the Federal Circuit rejected the notion that a patentee has an
19 obligation to bring the reference to the specific attention of the Examiner.

20 In contrast to *Fiskars*, the Examiner here expressly acknowledged considering the
21 information in question. See Bennett Decl., Exs. 8, 9 at 141-142, 148-149 (where Examiner
22 noted his consideration of the submitted references as follows: "All References Considered
23 Except Where Lined Through. / GA [Examiner's initials]"); see also Answer at ¶ 146 ("[t]he
24 prior art of record nor the prior art at large, alone or in combination, cannot remedy the
25 deficiencies of the Thal and Jobe references and thus the claims are allowed.").

26 If the failure of an Examiner to consider a submitted reference does not create an
27 obligation to bring the unconsidered reference to the specific attention of the Examiner (as
28 was the case in *Fiskars*), then undoubtedly there can be no obligation to bring a reference to

1 the Examiner's specific attention where it was considered as is the case here. "An applicant
 2 is not required to tell the PTO twice about the same prior art, on pain of loss of the patent for
 3 inequitable conduct." *Fiskars*, 221 F.3d at 1327. Thus, Melnick's alleged "failure" to bring
 4 the Millett Article and the Scott Statement to the attention of the Examiner cannot be material
 5 as a matter of law and cannot form the basis for an inequitable conduct claim.

6 **2. Arthrex has Not and Cannot Allege Facts Supporting any Intent to**
 7 **Deceive in Connection with the Submitted Information**

8 Arthrex's allegations of inequitable conduct regarding the Millett Article and Scott
 9 Statement also fail to meet the threshold for establishing intent. Under the pleading
 10 requirements set forth in *Exergen*, "[a]lthough 'knowledge' and 'intent' may be averred
 11 generally, [Federal Circuit] precedent, like that of several regional circuits, requires that the
 12 pleadings allege sufficient underlying facts from which a court may reasonably infer that a
 13 party acted with the requisite state of mind." *Exergen*, 575 F.3d at 1327. Arthrex does not
 14 allege specific facts demonstrating an intent to deceive on the part of Melnick. Rather, it
 15 generally avers an intent to deceive, stating only that Melnick's actions were "done
 16 knowingly, deliberately, and with the specific intent to deceive the PTO as to which
 17 references were the most material." Answer at ¶¶ 153. This allegation is legally insufficient.

18 As discussed above, Arthrex's allegations do not dispute that Melnick disclosed both
 19 the Millett Article and the Scott Statement to the Examiner. Based on this fact alone, it is
 20 hardly reasonable to infer that by disclosing the Millett Article and Scott Statement, Melnick
 21 intended to deceive the Examiner as to their relevance. *See Exergen*, 575 F.3d at 1329 n.5
 22 ("A reasonable inference is one that is plausible and that flows logically from the facts
 23 alleged, including any objective indications of candor and good faith.") The disclosure of this
 24 information is a clear and objective indication of Melnick's candor and good faith. Thus, the
 25 facts and circumstances that Arthrex has alleged "do not plausibly suggest any 'deliberate
 26 decision to withhold a known material reference' or to make a knowingly false
 27 misrepresentation – a necessary predicate for inferring deceptive intent." *Exergen*, 575 F.3d
 28 at 1331 citing *Molins PLC v. Textron, Inc.* 48 F.3d 1172, 1181 (Fed. Cir. 1995). Arthrex's

1 first theory of inequitable conduct therefore also fails to state a claim under the intent to
2 deceive element of *Therasense*.

3 **B. Arthrex Fails to State a Claim Based on the ‘622 Application Priority Date**

4 For its second theory of inequitable conduct, Arthrex contends that KFx failed to
5 inform the Examiner that the actual priority date for the ‘622 application was June 4, 2005,
6 the filing date of the KFx’s first non-provisional application (the ‘007 application). *See*
7 Answer at ¶ 122, ¶ 141. According to Arthrex, this information is “but-for” material because
8 the Examiner would have relied on the Millett Article to reject the claims had he known the
9 correct priority. Answer at ¶ 143.

10 Arthrex’s theory is wrong at numerous levels. First, Arthrex’s allegation regarding
11 the significance of the priority date is inconsistent with its allegation regarding the materiality
12 of when Millett performed the work for his article. The Millett work Arthrex relies upon was
13 prior to *any* of the KFx’s applications. Second, KFx had no duty to affirmatively represent
14 which particular prior filing supported the claims of the ‘622 application. Third, Arthrex has
15 alleged no basis to pick and choose the second of the three provisional applications as the one
16 the Examiner was supposedly led to believe supported the ‘622 patent application claims.
17 And finally, as with the all of its inequitable conduct claims, Arthrex has alleged no facts that
18 justify the requisite intent to deceive.

19 **1. The Priority Date is Not Material per Arthrex’s Allegations**

20 In order for Arthrex to state a claim with respect to KFx’s failure to provide an
21 affirmative representation regarding priority, the facts as alleged must demonstrate, at a
22 minimum, that the patent would not have issued if the Examiner had been made aware of the
23 June 4, 2005 priority date. *See Therasense*, 649 F.3d at 1291. Arthrex’s own allegations
24 demonstrate this is not so. It was immaterial whether the Examiner accorded the claims of
25 the ‘622 Application a priority date of June 4, 2005, or September 17, 2004, or some other
26 filing date, because the Millett work described in the Scott Statement predated *all* KFx
27 applications.

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1 Arthrex's allegations establish the immateriality of the priority date. Arthrex alleges,
 2 "[w]ithout having the Scott Statement or the work performed for the Millett Article
 3 specifically brought to his attention in the '620 and '622 Applications, the Examiner again
 4 did not specifically apply the work performed for the Millett Article in rejecting the pending
 5 claims." Answer at ¶ 140.⁵ Thus, according to Arthrex, the Examiner reasonably would have
 6 considered and applied the Millett work described in the Millett Article as prior art to the KFx
 7 applications if the Examiner were provided with the information in the Scott Statement.

8 The Scott Statement was provided to the Examiner. And, as discussed above, Federal
 9 Circuit precedent leaves no doubt that the Scott Statement was considered by the Examiner.
 10 *See Scripps Clinic*, 927 F.2d at 1582 ("[w]hen a reference was before the examiner, whether
 11 through the examiner's search *or the applicant's disclosure*, it can not be deemed to have
 12 been withheld from the examiner") (emphasis added); *accord* MPEP § 609.05 ("Examiners
 13 must consider all citations submitted in conformance with the rules...."). Having considered
 14 the Scott Statement, the Examiner was made aware that the Millett work described in the
 15 Millett Article was performed prior to the earliest of any of the applications filed by KFx.
 16 Accordingly, any failure to inform the Examiner of the June 1, 2005 priority date is
 17 immaterial and would not have impacted prosecution of the patent. *Cf. Trading Technologies*
 18 *Int'l. Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1362 (Fed. Cir. 2010) (affirming [under less
 19 stringent materiality standard] district court ruling that non-disclosed software was immaterial
 20 because it would not have changed the Examiner's analysis).

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 25 ⁵ Additional allegations made by Arthrex further demonstrate that the Scott Statement
 26 made it evident to any reasonable reader that the Millett work was performed prior to any
 27 priority date sought by KFx because the procedures in questions were performed "in the two
 28 years preceding publication of the [Millett] article." Answer at ¶ 100 ("Paragraph 4 of the
 Scott Statement states: 'I had a conversation with Peter Millett during which he told me that
 the procedures referenced in the 2004 article had been performed in the two years preceding
 publication of the article.'").

1 2. **Referencing Prior Applications in a Patent Specification Priority Claim**
2 **without Affirmatively Representing the Priority Date for Continuation**
3 **Claims is Not Inequitable Conduct**

4 Arthrex's second theory of inequitable conduct presupposes a duty that does not exist.
5 Accepting Arthrex's theory would establish a rule that an applicant is always obligated to
6 state the date of priority affirmatively for each claim in an application where the application
7 includes reference to one or more earlier applications. Thus, in any case where a claim made
8 in a later application is not entitled to priority back to all prior referenced applications, such
9 fact would justify a claim for inequitable conduct against the applicant under Arthrex's
10 reasoning. There is no such rule and KFx's failure to affirmatively state the priority date for
11 the '622 application claims during prosecution cannot form the basis for an inequitable
12 conduct claim.

13 Where the Federal Circuit has addressed the issue of inequitable conduct in the
14 context of priority claims, the court has made clear that it requires more than merely
15 referencing the disclosure of earlier applications for the benefit of priority. The Federal
16 Circuit decision in *Purdue Pharma v. Boehringer Ingelheim GMBH*, 237 F.3d 1359 (Fed. Cir
17 2000) is particularly instructive. There, the Federal Circuit affirmed a finding that an
18 inequitable conduct defense based on an improper claim of priority lacked substantial merit.
19 *Id.* at 1366-67. In doing so, the court stated that "[t]here is no evidence that [the patentee]
20 actively misled the examiner into believing that the '331 parent is not prior art, or that [the
21 patentee] argued that the claims of the asserted patents are entitled to the priority date of the
22 '331 parent." *Id.* at 1367.

23 The facts alleged by Arthrex are no different from those in *Purdue Pharma*. Just as
24 the patentee in *Purdue Pharma* did not actively mislead the Examiner into believing a
25 reference was not prior art, Arthrex makes no allegation here that Melnick actively misled the
26 Examiner into believing that Millett was not prior art.⁶ Additionally, just as the patentee in
27 _____

28 ⁶ Arthrex alleges that "Mr. Melnick diverted the Examiner's attention from the Scott

1 *Purdue Pharma* did not argue that the claims of the asserted patents are entitled to the priority
2 date of the parent application, Arthrex makes no allegation here that Mr. Melnick presented
3 such an argument. Arthrex alleges only that “Mr. Melnick also did not inform the Examiner
4 that the claims of the ‘622 Application were entitled to a priority date of September 1, 2005
5 [sic].” Answer at ¶ 141. Because the facts alleged by Arthrex in its Answer are no different
6 than those in *Purdue Pharma*, it has failed to state a claim of inequitable conduct. See
7 *Purdue Pharma*, 237 F.3d at 1367 (“These facts do not make out a case of inequitable
8 conduct.”)

9 The holding of *Purdue* makes complete sense because a priority claim in an
10 application serves numerous purposes. For example, it permits the applicant to maintain
11 continuity of priority in order to claim in a later continuation application what was disclosed
12 in the earliest application with an effective filing date of that earliest application. See
13 *Encyclopedia Britannica, Inc. v. Alpine Elecs. of America, Inc.*, 609 F.3d 1345, 1351 (Fed.
14 Cir. 2010) (an applicant must maintain continuity of priority back to any application to which
15 priority is later sought). The priority claim also affects the date an application or patent
16 effectively becomes prior art as to other applications. See *In re Giacomini*, 612 F.3d 1380,
17 1383-84 (Fed. Cir. 2010); see also *Purdue Pharma*, 237 F.3d at 1367. Further, the Manual of
18 Patenting Examining Procedure (“MPEP”) specifically provides that “[t]he inclusion of prior
19 application information in the patent does not necessarily indicate that the claims are entitled
20 to the benefit of the earlier filing date.” MPEP § 202.02.

21 Consistent with *Purdue Pharma*, where priority has factored into a finding of
22 inequitable conduct there has been more than mere reference to earlier applications for the
23 benefit of priority. For example, in *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir.
24

25 Statement since the Examiner was led to believe that Thal and Jobe were the most material
26 references disclosed in the December 2011 IDS.” Answer at ¶ 137. However, this is not an
27 allegation that Melnick misled the Examiner into believing that Millett was not prior art
28 because Arthrex makes no such claim. At most, this paragraph alleges that Melnick led the
Examiner to believe that Thal and Jobe were the most material references. Because there is
no duty to specifically call the most material references to the attention of the Examiner (see
discussion in Section IV.A.1 *supra*), this conduct cannot be considered materially misleading.

2007), the Federal Circuit affirmed inequitable conduct based, in part, on priority claims, albeit under the less exacting pre – *Therasense* standard. The applications at issue there failed to comply with the statutory co-pendency and cross reference requirements and the inventor also wrote letters contemporaneous with the priority claims evidencing his concern about securing patents for new designs in light of unspecified prior art. *Id.* at 1233.

In sum, Arthrex’s allegations regarding the priority claim at issue here are insufficient as a matter of law to state a claim for inequitable conduct.

3. Arthrex Alleges No Facts to Support its Premise that the Examiner Assumed a Priority Based upon the Second Provisional Application

Arthrex’s theory is premised on the assumption, which is supported by no factual allegations, that the Examiner relied upon the second of three provisional applications as the priority date. The second provisional application was filed *before* the publication of the Millett Article. But the third provisional application was filed *after* publication of the Millett Article and thus could not have impacted the Examiner’s consideration of whether the Millett Article was prior art. Arthrex makes no allegation as to why or how the Examiner would ignore the contents of the three provisional applications and simply conclude the second provisional application provided the priority date for the ‘622 patent application. For this additional reason, Arthrex has not, and cannot, establish the materiality of KFx’s failure to affirmatively inform the Examiner as to which prior art application provided the priority date for the ‘622 application claims.

4. Arthrex’s Conclusory Allegation of Intent to Deceive also Fails as a Matter of Law

Arthrex’s allegations of intent to deceive based on the priority date also fail to state a claim because it is not plausible to infer that Melnick intended to deceive the Examiner based on the facts alleged. There are several “objective indications of candor and good faith” reflected in Arthrex’s allegations which make unreasonable any inference that Melnick acted with deceptive intent. *See Exergen*, 575 F.3d at 1329 n.5 (“A reasonable inference is one that

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1 is plausible and that flows logically from the facts alleged, including any objective indications
2 of candor and good faith.”)

3 The first objective indication of candor and good faith is the fact that Melnick was not
4 obliged or otherwise required to affirmatively represent the date of priority, even if the
5 continuation claims were not entitled to the filing date of the earlier filed provisional
6 applications. *See Purdue Pharma*, 237 F.3d at 1367 (no inequitable conducts “in the mere act
7 of claiming priority to an earlier patent....”).

8 The second objective indication of candor and good faith arises out of the PTO rules
9 governing priority claims. As noted previously, “[t]he inclusion of prior application
10 information in the patent does not necessarily indicate that the claims are entitled to the
11 benefit of the earlier filing date.” MPEP § 202.02. Thus, it would be illogical to infer that
12 Melnick believed that by making the priority claim, the PTO would be deceived as to the
13 materiality of the Millett Article and the Scott Statement.

14 The third objective indication of candor and good faith stems from Melnick’s
15 submission of the Scott Statement in the December 1, 2011 IDS. The Scott Statement
16 indicated that Millett had told Scott that “procedures referenced in the 2004 article had been
17 performed in the two years preceding publication for the article” and that “all of the
18 procedures were performed by tying knots as described in the 2004 article.” Answer at ¶¶
19 100-101. Because the Scott Statement made it evident that the Millett work was performed
20 prior to the earliest KFx application, it is implausible to infer that Melnick intended to
21 deceive the Examiner regarding the prior art status of Millett.

22 In sum, Arthrex has not alleged facts from which an intent to deceive is a plausible
23 inference. Rather, the facts alleged include objective indications of candor and good faith
24 inconsistent with an intent to deceive. Accordingly, Arthrex’s second theory of inequitable
25 conduct also fails to state a claim under the intent to deceive element.

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C. **Arthrex Fails to State a Claim Based on KFx's Submission of the Arthrex Invalidity Contentions to the PTO**

1. **Arthrex's Theory is Unrecognized**

After the Federal Circuit's admonition in *Therasense* that inequitable conduct had become an overused plague in patent cases, Arthrex seeks once again to expand the doctrine with its third theory of inequitable conduct. Arthrex's third theory of inequitable conduct would leave applicants facing inequitable conduct charges any time they do not affirmatively withdraw an application from issuance if they learn of any information arguably relevant to the application after examination has closed. Because the law imposes no such duty to withdraw an application from issuance, inequitable conduct cannot be grounded on an alleged failure to comply with such duty.

A finding of inequitable conduct requires that the applicant be found to have ***misrepresented or withheld material information***. See *Am. CalCar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011) (emphasis added). Here, no material information has been alleged to have been withheld or misrepresented. See Answer at ¶¶ 158-160. The alleged wrong was KFx's failure to petition the PTO to withdraw its patent from issuance so that the Examiner could consider the Arthrex '311 patent Invalidity Contentions, which were served on KFx after examination had closed. Recognizing such a theory would put KFx and other applicants in an unworkable scenario where they could never allow a patent application to issue without later facing an inequitable conduct charge where their competitor provided notice of arguably relevant information shortly before issuance.

2. **Arthrex has Failed to Plead the Requisite Materiality**

Arthrex's allegations regarding the Invalidity Contentions also fail due to Arthrex's failure to plead materiality as required by *Exergen*. *Exergen*, 575 F.3d at 1327 ("in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO"). Arthrex merely alleges the Invalidity Contentions "are material." See Answer at ¶ 157. This is insufficient under *Exergen*. Arthrex does not provide any reason why the

Invalidity Contentions for the '311 patent are "but-for" material with respect to the continuation application which has different claims. For this additional, albeit less fundamental, reason, the affirmative defense should be stricken and the counterclaim of inequitable conduct dismissed for failing to adequately plead the requisite amount of detail to establish materiality.

3. Arthrex's Allegations Regarding Intent to Deceive Concerning the Invalidity Contentions are Insufficient

In its continued effort to accuse a professional of deceptive intent with no facts to support the accusation, Arthrex characterizes a phrase in the IDS Melnick submitted with the Invalidity Contentions as an alleged "knowingly false representation." Answer at ¶ 168. Arthrex alleges that Melnick's statement that the IDS was "listing references for consideration" was "a knowingly false representation" because Melnick knew that the references would not be considered but merely placed in the file. Answer at ¶¶ 159-162, 168. Arthrex must blind itself to the rest of the four sentence document to somehow justify this accusation. The document shows Arthrex's labeling of the representation as "false" has no basis in fact. The entire substance of the document submitting the IDS is as follows:

References and Listing

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

Timing of Disclosure

This Information Disclosure Statement is being filed after the mailing date of a final action or after the mailing date of a Notice of Allowance. Please place these references in the file in accordance with 37 CFR 1.97(i).

See Bennett Decl. Ex. 10 at 150-151.

Melnick specifically referenced the applicable rule and noted the IDS was filed after the mailing of a Notice of Allowance. Melnick also requested that the PTO "place these references in the file in accordance with 37 C.F.R. 1.97(i)." Arthrex's allegations of a "false representation" is nothing more than a characterization or label unsupported by fact.

Further, Melnick's use of the phrase "for consideration" also cannot provide the foundation for inequitable conduct because Arthrex fails to connect the alleged deception with the PTO's decision to allow the '622 application to issue. *See Answer at ¶ 168.* Arthrex does not allege that the Melnick's statement that the Invalidity Contentions were submitted "for consideration" had any impact on the PTO's decision to issue the patent. If anything, this allegedly misleading statement could be interpreted as attempting to deceive the PTO into actually considering the Invalidity Contentions after examination was closed.

Finally, Arthrex's allegation also fails to satisfy the rigorous pleading requirements of *Exergen*. Pleading intent under Rule 9(b) requires that "[t]he relevant 'conditions of mind' for inequitable conduct include: (1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1326–28. Although Arthrex alleges that Melnick knew of the "falsity" of his use of the phrase "for consideration" in submitting the IDS to be placed in the file, but Arthrex does not allege that Melnick knew the alleged falsity of the statement was **material to patentability**. Accordingly, Arthrex has failed to adequately plead that Melnick had knowledge of the alleged materiality, and its allegations fail to state a claim.

**V. ARTHREX SHOULD NOT BE GIVEN LEAVE TO
AMEND BECAUSE NO AMENDMENT COULD LEAD TO
ANY VIABLE CLAIM OF INEQUITABLE CONDUCT**

Arthrex may seek leave to amend its allegations to correct the defects in its inequitable conduct allegations. It should not be permitted to do so. Although parties are generally granted leave to amend where pleadings are dismissed under Rule 12, there is an important exception to that rule. A party should not be permitted to amend where any amendment would be futile and could not save the claim. *Polich v. Burlington Northern, Inc.*, 942 F.2d 1467, 1472 (9th Cir.1991). In this case, there are no additional facts that Arthrex could plead in order to cure the fatal flaws in its allegations of inequitable conduct. The acts alleged to be inequitable conduct are simply insufficient as a matter of law to set forth any viable claim of inequitable conduct.

**VI. THE DATE FOR KFX'S ANSWER TO REMAINING
COUNTERCLAIMS SHOULD BE EXTENDED**

The law is not entirely settled with respect to a party's obligation to file an answer when a motion to dismiss is filed with respect to some, but not all, claims of a pleading. *See Ideal Instruments, Inc. v. Rivard Instruments, Inc.*, 434 F. Supp. 2d 598, 637-640 (N.D. Iowa 2006) (holding that "a motion pursuant to Rule 12(b), even one that challenges less than all of the claims asserted in the complaint or other pleading, extends the time to answer as to all claims in the pleading"); *Godlewski v. Affiliated Computer Servs., Inc.*, 210 F.R.D. 571, 572 (E.D. Va. 2002) (holding that Rule 12(b)(6) motions extend time for answering entire pleading); *cf. Gerlach v. Mich. Bell Tel. Co.*, 448 F. Supp. 1168, 1174 (E.D. Mich. 1978) (holding that Rule 12(b) motion does not alter the time for filing an answer). Further, it would be inefficient for KFx to now answer portions of Arthrex's counterclaim and then possibly answer other portions after this motion is resolved. Accordingly, KFx respectfully moves for a continuance to file a single answer to Arthrex's counterclaims following a decision on the instant motion to dismiss.

VII. CONCLUSION

For the foregoing reasons, KFx respectfully requests that this Court grant its motion to dismiss Arthrex's inequitable conduct counterclaims as to the '942 and '969 patents without leave to amend and also strike the corresponding affirmative defense.

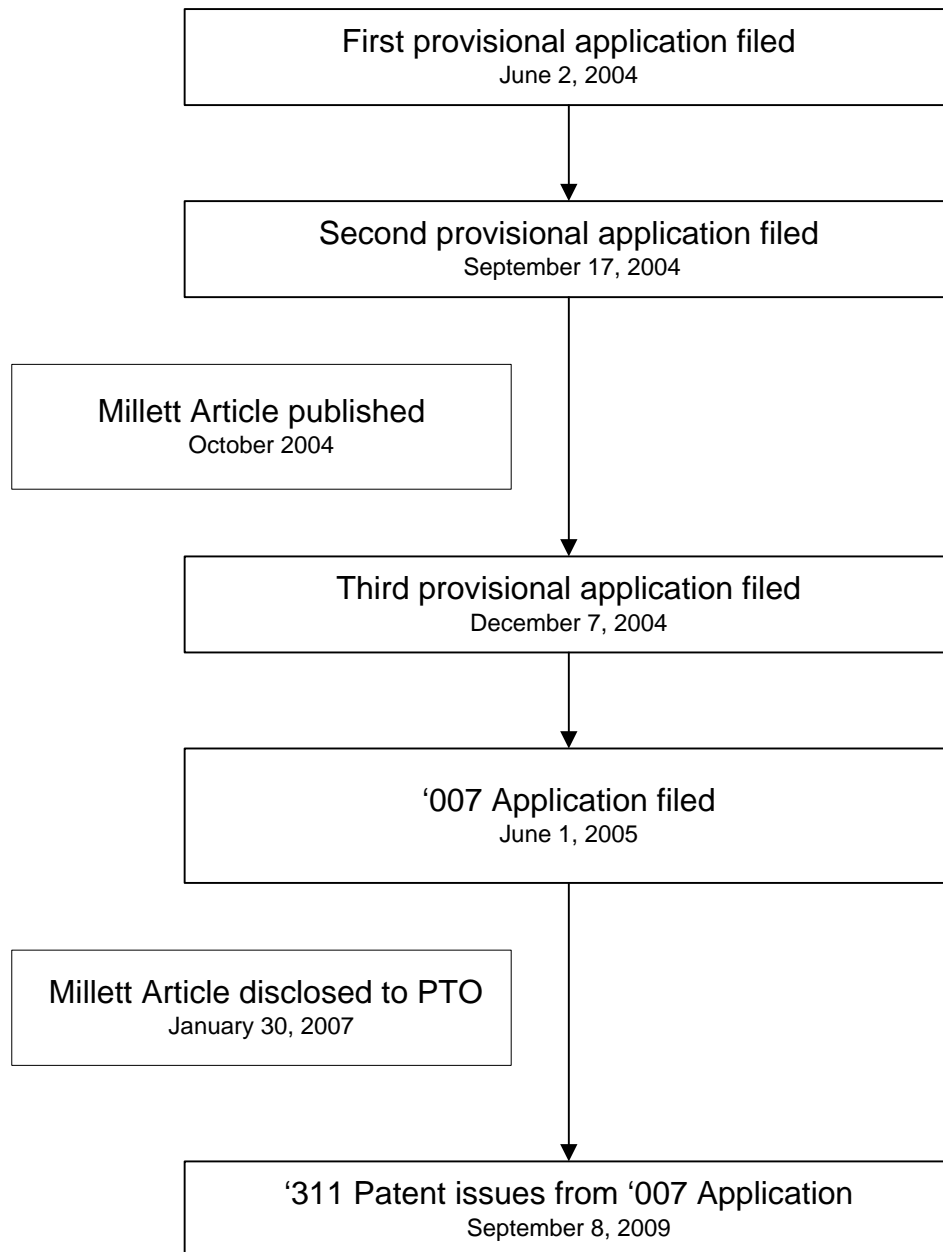
Respectfully submitted,

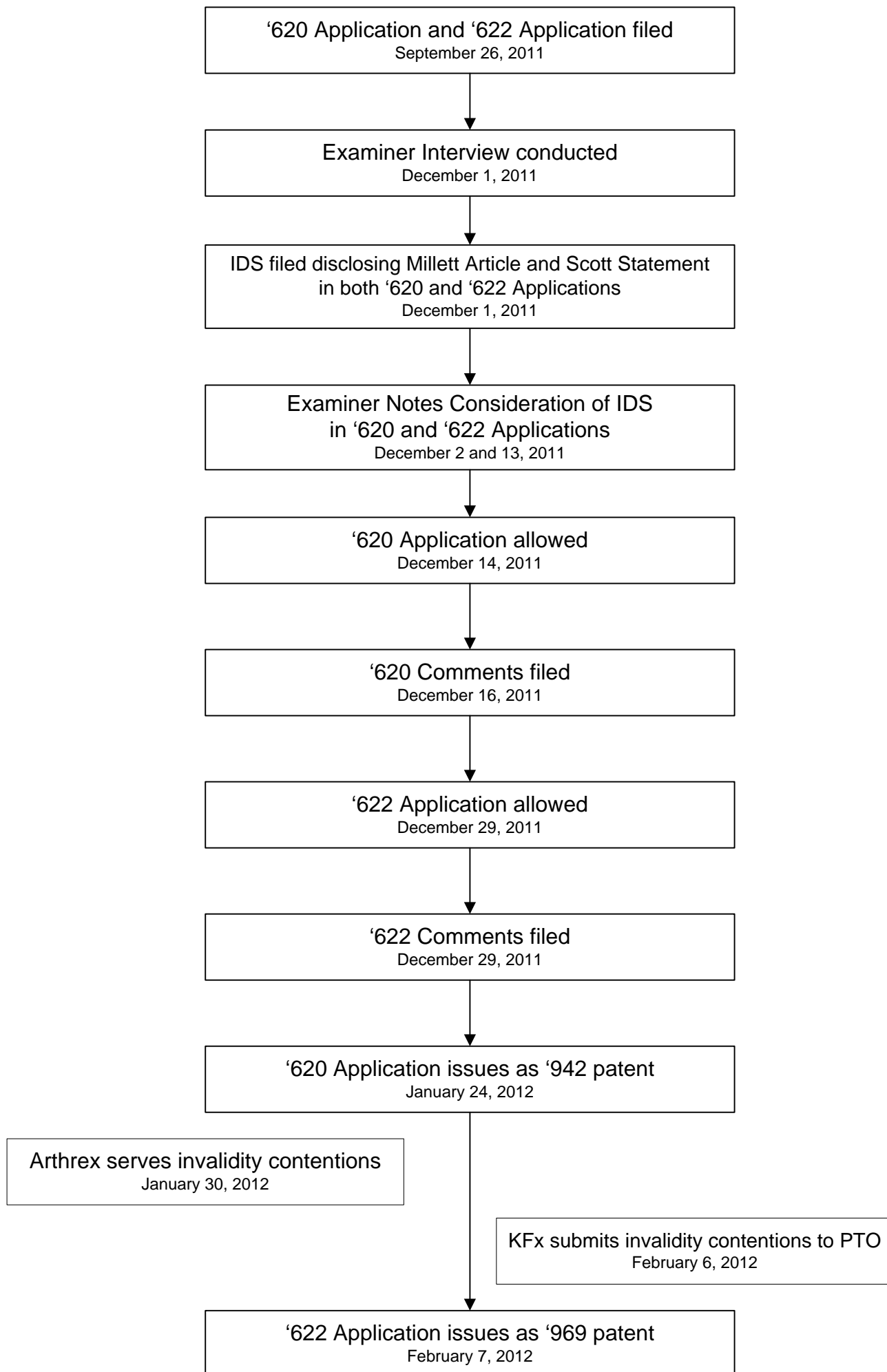
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May 24, 2012

By: s/Joseph F. Jennings
Joseph F. Jennings
Phillip A. Bennett

Attorneys for Plaintiff
KFx Medical Corporation





PROOF OF SERVICE

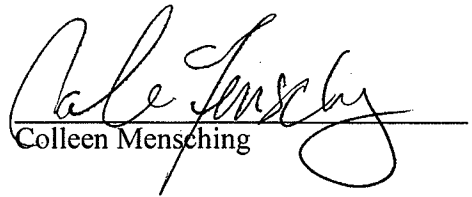
I hereby certify that on May 24, 2012, I caused the **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION TO (A) DISMISS DEFENDANT'S COUNTERCLAIM FOR INEQUITABLE CONDUCT IN CONNECTION WITH U.S. PATENTS 8,100,942 AND 8,109,969; (B) STRIKE THE CORRESPONDING AFFIRMATIVE DEFENSE; AND (C) EXTEND TIME TO ANSWER REMAINING COUNTERCLAIM ALLEGATIONS** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

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I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the forgoing is true and correct.

Executed on May 24, 2012, at San Diego, California.


Colleen Mensching

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